National Institutes of Health Clinical Center,
Department of Transfusion Medicine, Cell Processing Section
Bethesda, MD 20892 FDA Registration # 1174694

STANDARD OPERATING PROCEDURE

DTM-SOP-5118
New: 09/2004
Date in Service: 10/2004
Date Removed from Service: _____

Procedure Title: CRIS Ordering Overview and Instructions

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Annual Review:

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Reviewer	Date	Medical Director	Date
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Reviewer	Date	Medical Director	Date

CRIS Ordering Overview and Instructions

PRINCIPLE OR PURPOSE

CRIS (Clinical Research Information System) is a medical laboratory information system (LIS) that supports patient care, research and management at the Warren Grant Magnuson Clinical Center and the Mark O. Hatfield Research Center. The system consists of two distinct integrated information cores - Clinical Data Repository and the Clinical Data Warehouse.

- The Clinical Data Repository is the hub of all patient and operational related interactions. Within in its operation it stores patient demographics, lab results, pharmacy orders, the hospital service formulary, information from referring physicians, physician notes, links to patient images in the radiology imaging system and multidisciplinary documentation of care.

- The Clinical Data Warehouse will centralize historical patient data for retrieval and analysis. The Data Warehouse ancillary system will focus on tracking information in support of safety and organizational efficiency initiatives.

Since the Cell Processing Section (CPS) is a service based operation and plays an integral role within the Clinical Center, it is important for those who use CPS services have a guide to properly navigate the CRIS system regarding requests that pertain to CPS operations.

POLICY

Cell Processing Section (CPS) adheres to regulations/standards and guidelines stipulated by the Food and Drug Administration (FDA); American Association of Blood Banks (AABB); Health and Human Services (HHS); Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments of 1988 guidelines.

SCOPE

All requests for CPS services must be submitted through CRIS. The core of CPS services is handled within several operations. These operations are detailed within this SOP as working instructions. The working instructions will reflect what is required to iniate either an order or service request pertaining to CPS operations. Each Working Instruction will have a “Scope” assigned to it and will detail its use on how to complete a request.

RESPONSIBILITIES

Clinical center staff members who work in conjunction with CPS services and/or operations are responsible for proper order/request entry using the CRIS system.

PROCEDURAL NOTES: Work instructions within this SOP are a guide for nursing/physician staff members on the listed tasks and do not entail all aspects of using the CRIS system on the ward/clinic or in CPS.

LISTING OF WORKING INSTRUCTIONS

- 5118-1 Request CPS Processing of Clinical Product
- 5118-2 Request CPS Processing of Product for Research Use only (Exception: Protocol 99-CC-0168, Dr.Child's Elutriation)
- 5118-3 Ordering Pre CD34 Test Independent of Apheresis Procedure
- 5118-4 Ordering CPS Product for Infusion through the Human Cell/Tissue Component Order Set
- 5118-5 Further Manufacturing Request (Not available until March 2005)
- 5118-6 Processing for Non-CRIS Registered Recipient (Not available until March 2005)
- 5118-7 Access/Viewing CRIS Order
- 5118-8 Generating Admission Labels
- 5118-9 Completing/Canceling CRIS Order

REFERENCE:

CRIS (Clinical Research Information System) Fact Sheet
http://cris.cc.nih.gov/public/project.html

Document History

Date_____	Additions/Revisions/Deletions:
09/2004	New Procedure

INSTRUCTION # 5118-1
Request CPS Processing of Clinical Product via Human Cell/Tissue Processing Order

1. SCOPE:

Cellular therapy products, intended for human use, to be processed in the Cell Processing Section of the Department of Transfusion Medicine must be requested through CRIS via the **Human Cell/Tissue Processing Order**. The CRIS order is required even when there is a concurrent paper request form. Since this order must be submitted under the recipient, the recipient must be registered in CRIS. Each order is to request processing on a single product on a given day. If a protocol requires processing of more than one product on more than one day, a separate order must be submitted for each product to be processed on a given day.

2. PROCEDURE:

2.1 Ordering from an Individual Order Request

1) Select the assigned patient/recipient from the **Patient List Display**. Click on **Enter Order** icon.

2) Under "Requested By" select **Other** to designate principle investigator (PI) of protocol. Type in PI's last name and select **Written** as the "Source".

3) Under "Start of Browse" select **Transfusion Medicine** → select **Human Cell/Tissue Products**→ scroll to **Human Cell/Tissue Processing Order**. Click **Add.**

4) Complete **DTM Human Cell/Tissue Processing Order Request** as follows (highlighted fields require entry):

   Priority- Routine

   Reason for Stat or Priority Precedence – No Entry

   Requested Date- Date Product to be Processed

   Note: More than one processing date requires an order for each date.

   Donation Type- Enter Donation Type

   Note: this is the type of donation for this recipient.

   Donation Types Currently in Use:
   Autologous – product for which the donor is the recipient
   Directed (Allogeneic) – product from a family related donor

Human Cell or Tissue Type- Select Product from Drop List

Note: If the product type is in question or does not appear on the list of available product types, contact CPS Scheduling Coordinator for assistance. Cord Blood, Human Pancreatic Islet Cells and Monocytes are for CPS use only.

Lymphocytes – Manipulated: lymphocyte products from which donor lymphocyte aliquots for donor lymphocyte infusion (DLI) are manufactured
Marrow: bone marrow
Mononuclear Cells: mononuclear cell products to be further processed (i.e., elutriation)
Peripheral Blood Stem Cells

Donor Information (note: for autologous donor, provide information even if recipient = donor):

Donor Last Name- Donor's Last Name

Donor First Name- Donor's First Name

Donor MRN- Donor's Medical Record Number (MRN)

Donor Date of Birth- Donor's Date of Birth

Cryopreserve the Donation- Select Yes or No.

Note: If product is to be collected and given as a fresh infusion (no cryopreservation), a Human Cell/Tissue Component Order set request will be submitted by a CPS staff member for PI.

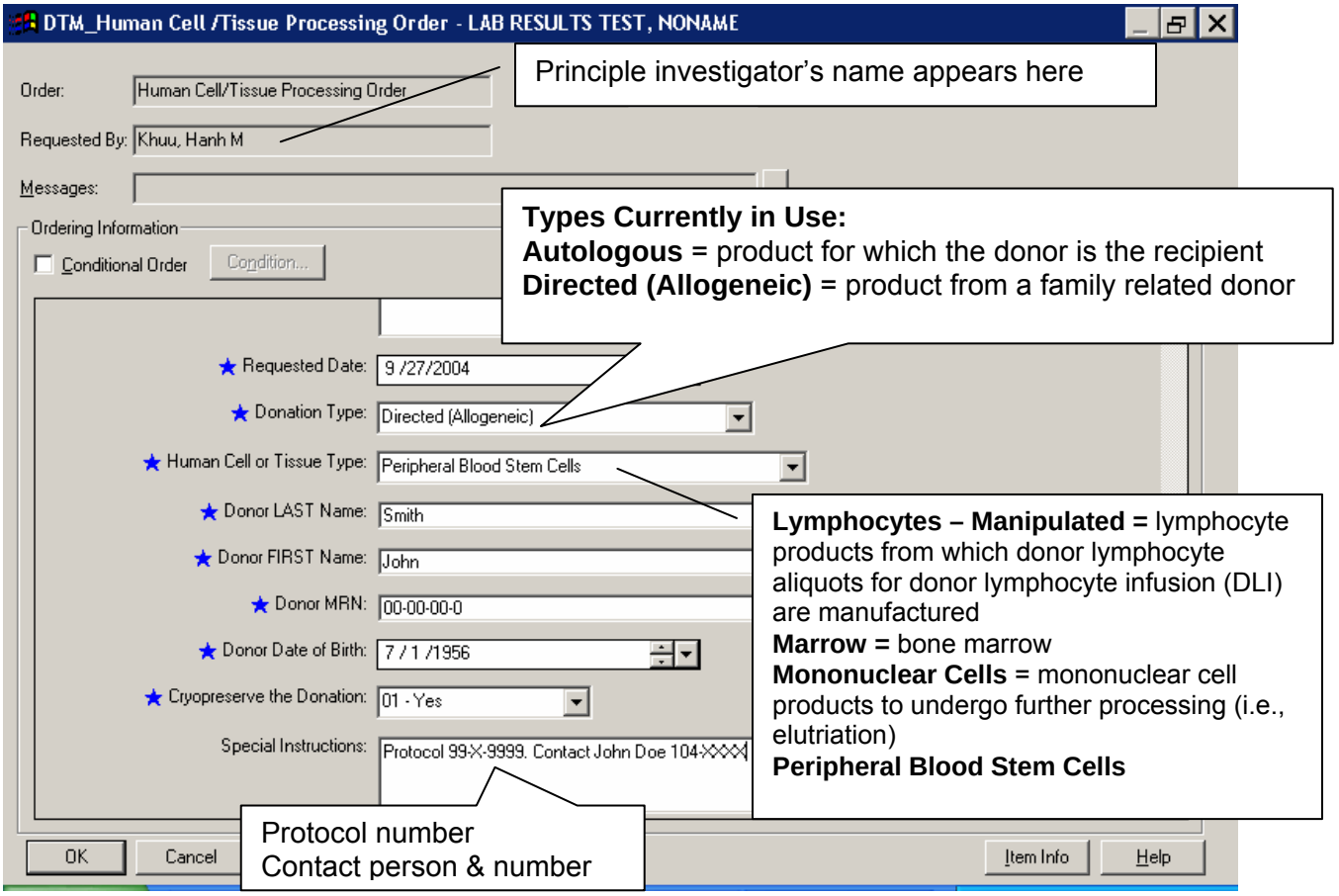
Special Instructions – Required by CPS

1) **Protocol number** which will be used as reference protocol for processing instructions

Note: Protocol number appearing in CRIS header on requisition may not be accurate and will not be used by CPS staff.

2) **Contact person & number**

Note: Space allotted will limit free text entry to approximately 150 characters.



5) Review and click **OK** if complete. Click **Submit,** if order is ready for submission.

   Note: If you need to review order fields again, select order and EDIT.

6) After order is submitted click on **Orders** tab. The Clinical Manager will appear with appropriate orders listed under **Transfusion Medicine** with a **Pending Collection** status.

7) Order entry for this CPS order is now complete.

3. REFERENCES:

CRIS Practice Exercise Workbook, Non-Prescriber Order Entry, NIH, 2004.

INSTRUCTION # 5118-2
Request CPS Processing of Product for Research Use Only via the Research Human Cell/Tissue Processing Service

(Exception: Elutriation of products collected on 99-C-0168)

1. SCOPE:

Cellular therapy products, for research use only, to be processed in the Cell Processing Section of the Department of Transfusion Medicine must be requested through CRIS via the **Research Human Cell/Tissue Processing Service**. The CRIS order is required even when there is a concurrent paper request form. Each order is to request processing on a single product on a given day. If a protocol requires processing of more than one product on more than one day, a separate order must be submitted for each product to be processed on a given day.

2. PROCEDURE:

2.1 Ordering from an Individual Order Request

1) Select assigned donor from **Patient/Donor List Display**. Click **Enter Order** icon.

2) Under "Requested By" select **Other** to designate principle investigator (PI) for protocol. Type in PI's last name and select **Written** as the "Source".

3) Under "Start of Browse" select **Transfusion Medicine** → select **Human Cell/Tissue Products** → scroll to **Research Human Cell/Tissue Processing Svc**. Click **Add.**

4) Complete **DTM Research Human Cell/Tissue Processing Service Request** as follows (highlighted fields require entry):

Priority- Routine
Reason for Stat or Priority Precedence- No Entry
Requested Date- Date Product to be Processed
Note: More than one processing date requires an order for each date.

Donation Type- Research

Human Cell or Tissue Type- Select Product From Drop List
Note: If product type is in question or does not appear on list of available product types, contact CPS Scheduling Coordinator for assistance. Cord Blood, Human Pancreatic Islet Cells and Monocytes are for CPS use only.

Lymphocytes – Manipulated: lymphocyte products from which donor lymphocyte aliquots for donor lymphocyte infusion (DLI) are manufactured
Marrow: bone marrow
Mononuclear Cells: mononuclear cell products to be further processed (i.e., elutriation)
Peripheral Blood Stem Cells

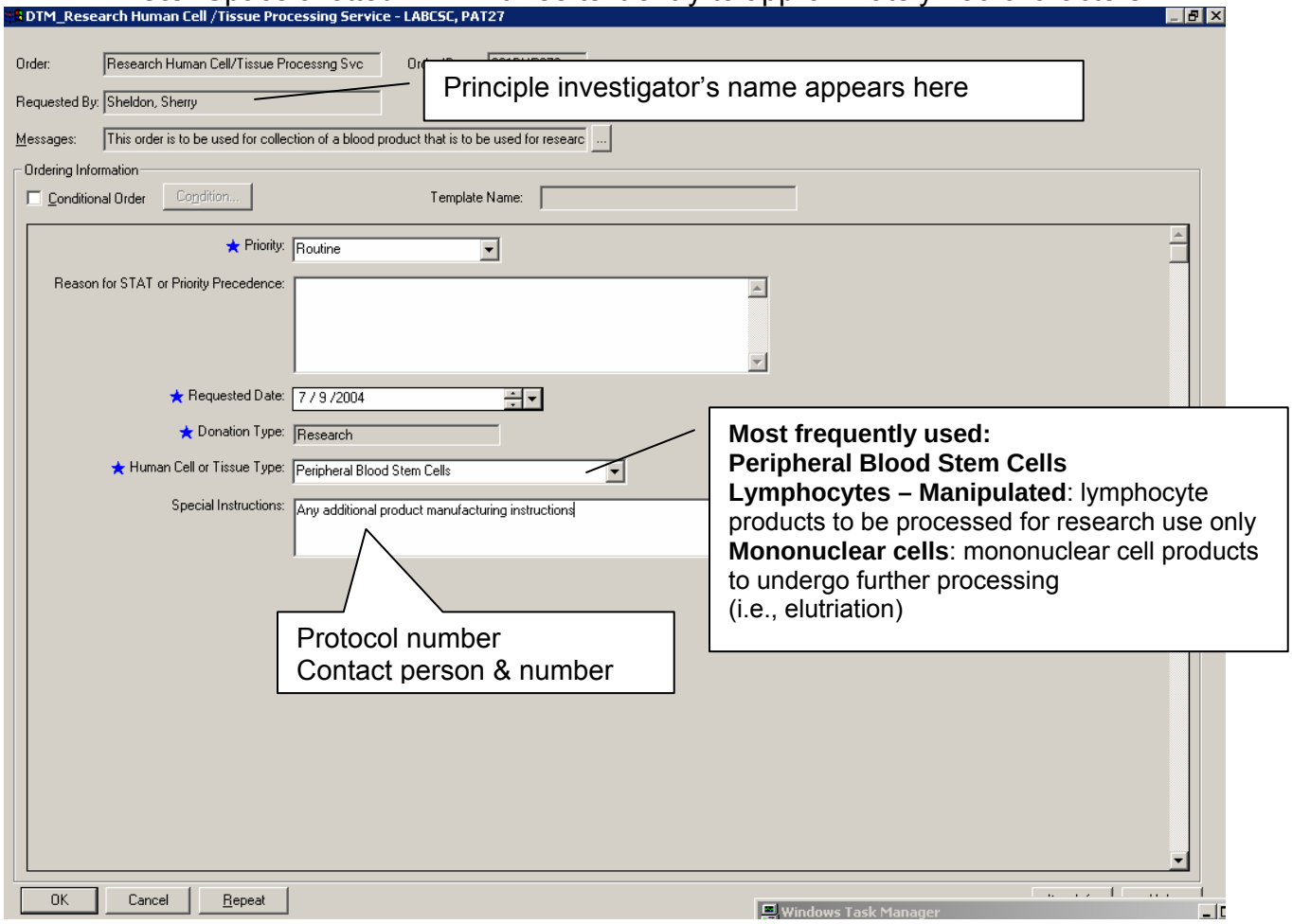
Special Instructions – Required by CPS

1) **Protocol number** which is used as reference protocol for processing instructions

Note: Protocol number appearing in CRIS header on requisition may not be accurate and will not be used by CPS staff.

2) **Contact person & number**

Note: Space allotted will limit free text entry to approximately 150 characters.



5) Review and click **OK** if complete. Click **Submit,** if order is ready for submission.
Note: If you need to review order fields again, select order and EDIT.

6) After order is submitted click on **Orders** tab. The Clinical Manager will appear with appropriate orders listed under **Transfusion Medicine** with a **Pending Collection** status.

7) Order entry for this CPS order is now complete.

3. REFERENCES:

CRIS Practice Exercise Workbook, Non-Prescriber Order Entry, NIH, 2004.

INSTRUCTION # 5118-3

Ordering Pre-CD34 Test Independent of Apheresis Procedure

1. SCOPE:

This is a special laboratory test for enumeration of CD34+ cells that is performed on whole blood samples collected independent of an apheresis procedure. The test may only be ordered with prior notification to the Cell Processing Section Service Coordinator. Written or verbal orders are not acceptable because this is a laboratory test that must be requested in CRIS. Order entry is performed under the person from whom the sample is drawn (i.e., either a donor or recipient). Each order request is for a single collection. If the protocol requires that specimen collection be done over a period of more than one day, (i.e., Day 0, Day 3, and Day 5) then order entries must be submitted for each day of specimen collection.

2. PROCEDURE:

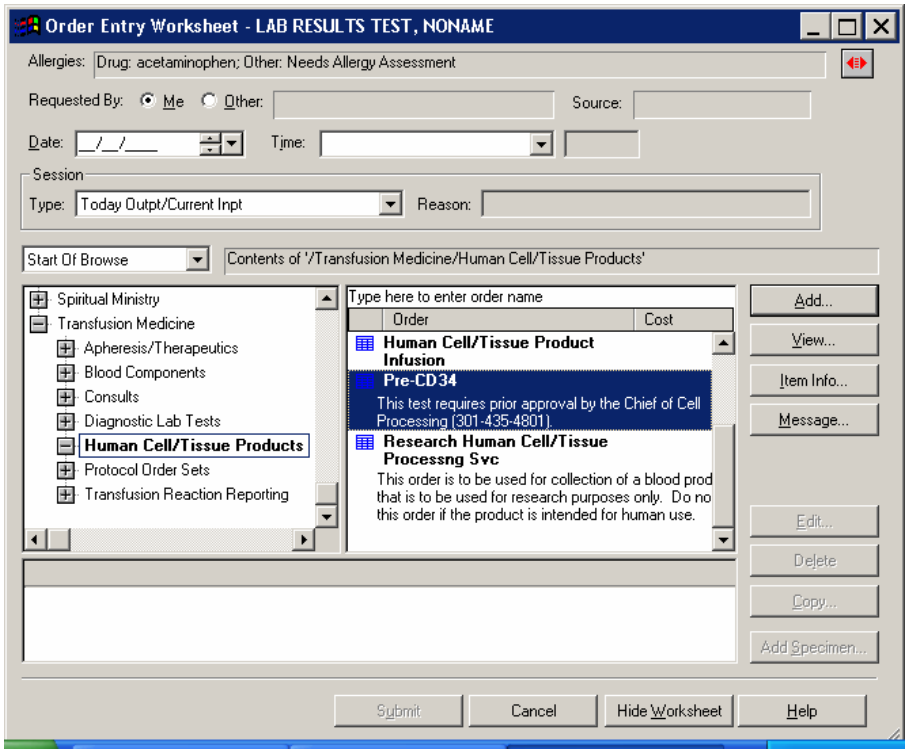
2.1 Ordering from an Individual Order Request

1) Select assigned donor or recipient from **Patient/Donor List Display**. Click on **Enter Order** icon.

2) Under "Requested By" select **Other** to designate principle investigator (PI) for protocol. Type in the PI's last name and select **Written** for "Source".

3) Under "Start of Browse" select **Transfusion Medicine** → select **Human Cell/Tissue Products**→ scroll to **Pre-CD34**.

4) Select **Pre-CD34,** click **ADD**.

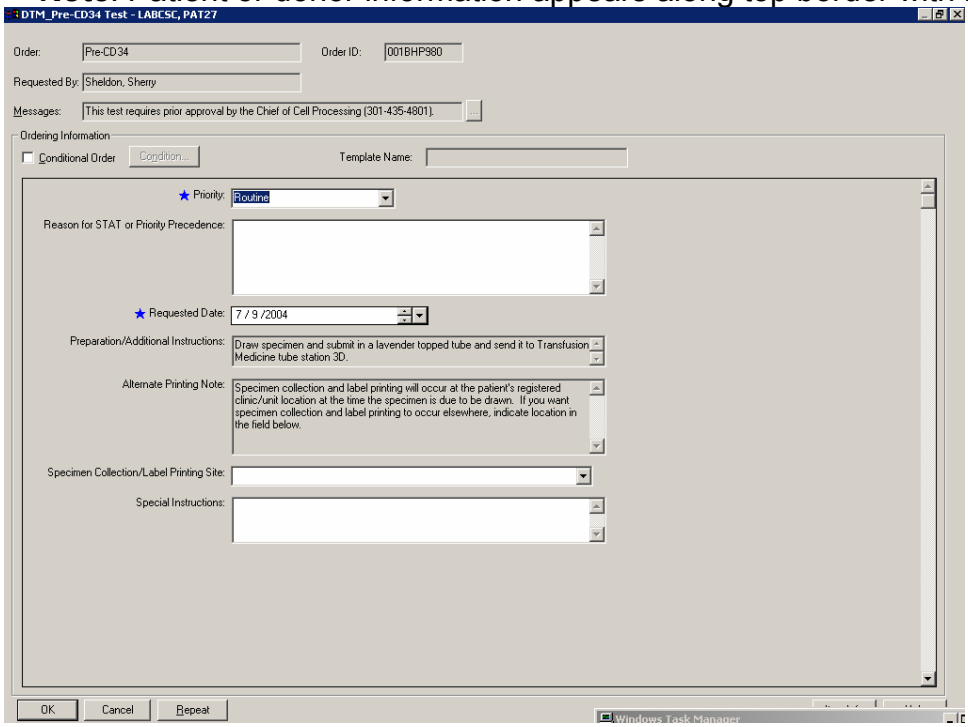


5) **DTM Pre-CD34 Test** entry screen will appear.

6) Complete **DTM Pre-CD34 Order Request** as follows (highlighted fields require entry):

Priority- Routine, unless CPS is notified of an emergent situation
Reason for Stat or Priority Precedence- Comment required if order is **not** routine
Requested Date- Date specimen collected
Note: A Pre-CD34 order request is required for each specimen collected.
Preparation/Additional Instructions- No Entry
Alternate Printing Note- "Specimen collections and labeling printing will occur at the patient's registered clinic/unit location at the time the specimen is due to be drawn. If you want specimen collections and label printing to occur elsewhere, indicate location in the field below.
Specimen Collection/Label Printing Site- Used in conjunction with Alternate Printing Note. If specimen is not drawn at site of patient's registered clinic/unit location, please select from pick list the nearest label printing site available to obtain specimen labels.
NOTE: Specimens that are not labeled in accordance with Clinical Center policies are not accepted by CPS.

Note: Patient or donor information appears along top border with name of order.

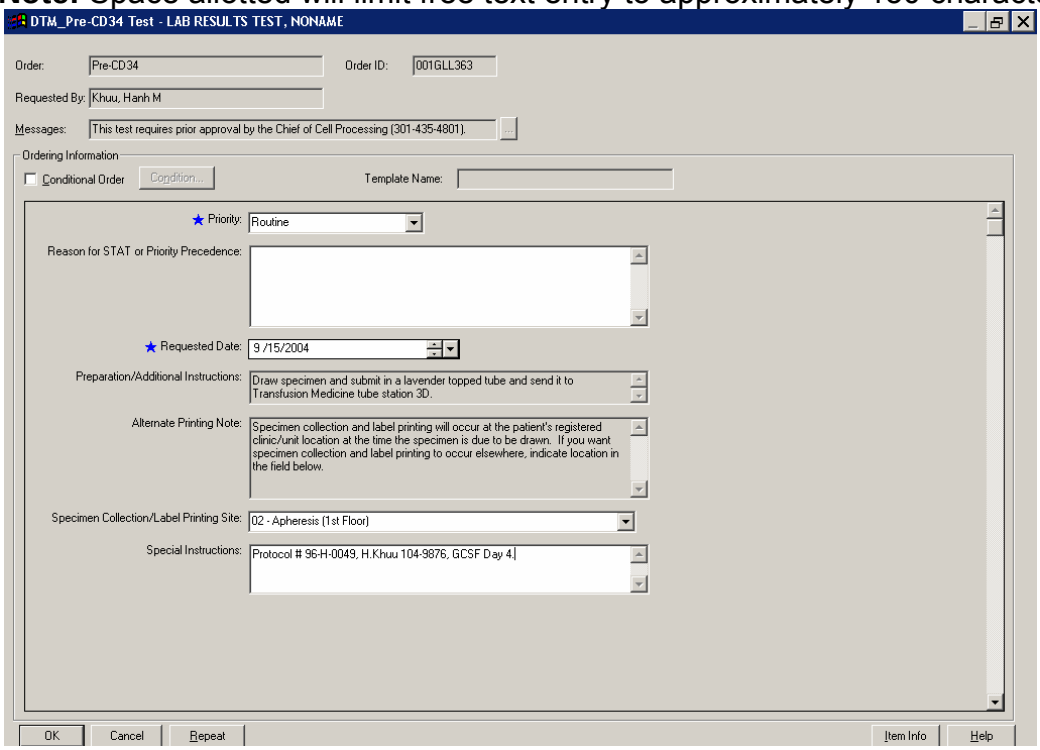


Special Instructions- Required by CPS

1) Protocol number
2) Contact person & number for reporting results

3) Additional sample identifiers (i.e., day 0, day 4)

Note: Space allotted will limit free text entry to approximately 150 characters.



7) If **DTM Pre-CD34 Order Request** is complete click **OK** button in lower left corner.

8) **Order Entry Worksheet** will reappear. Click **Submit**.

9) After order is submitted click on **Orders** in donor/recipient (patient) record.

10) Clinical Manager will display order under **Transfusion Medicine** with **Pending** status.

11) Order entry for Pre-CD34 order is now complete.

3. REFERENCES:

CRIS Practice Exercise Workbook, Non-Prescriber Order Entry, NIH, 2004

INSTRUCTION # 5118-4
Ordering CPS Product for Infusion via Human Cell/Tissue Component Order Set

1. SCOPE:

CPS products intended for infusion to patients must be requested in CRIS, even if there is a concurrent paper request form. Infusions of CPS products are ordered via **Human Cell/Tissue Component Orders**. Within this order set are a LAB component order and a NURSING infusion order. The LAB order is interfaced with the clinical laboratory's ancillary computer system (SoftLab). SoftLab allows for tracking of products distributed through CPS. The NURSING infusion order provides instructions to nursing staff administering the product.

A CPS Human Cell/Tissue Component Order is an order set that requires both a Component and an Infusion Order to be submitted.

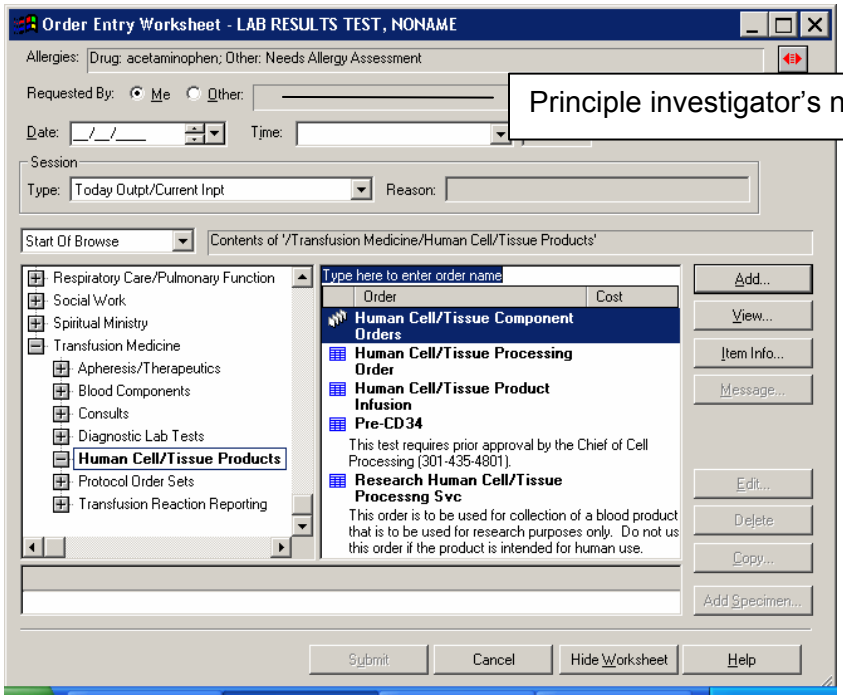
2. PROCEDURE:

2.1 Ordering from an Order Set

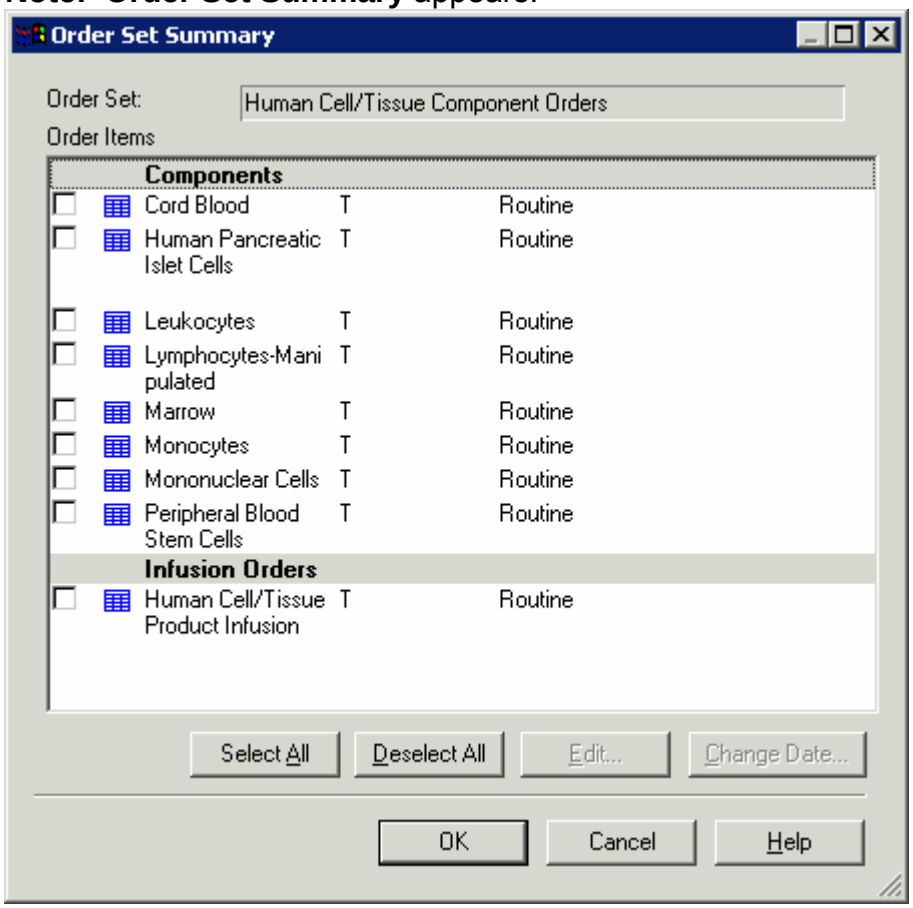
1) Select assigned patient/recipient from **Patient List Display**. Click on **Enter Order** icon.

2) Under "Requested By" select **Other** to designate principle investigator (PI) for protocol. Type in the PI's last name and select **Written** for "Source".

3) Under "Start of Browse" → select **Transfusion Medicine** → select **Human Cell/Tissue Products** select **Human Cell/Tissue Component Orders**. Click **ADD**.



Note: Order Set Summary appears.



4) Select **Component/ Product Type** for infusion. Click **EDIT.**
Note: If there is a question of what product to order, contact CPS Scheduling Coordinator for verification.
Note: It is possible to select more than one product type.

5) Complete **DTM CPS Components** (highlighted fields require entry) as follows:
Note: A separate order is required for each component **type** (e.g., a PBSC infusion event with a T cell addback requires a PBSC component order and a Lymph component order). See ATTACHMENT 1 for ordering PBSC with T cell addback. To know what products are available for a recipient request a Summary of Clinical Products (DTM-FORM-5111) from the CPS Service Coordinator.

Priority- Routine

Reason for Stat or Priority Precedence- No Entry

Requested Date- Date of Infusion

Product Number- Enter Alpha Numeric Identifier

Number of Units Requested- Up to 6 units selected from pick list (additional unit numbers are typed in)

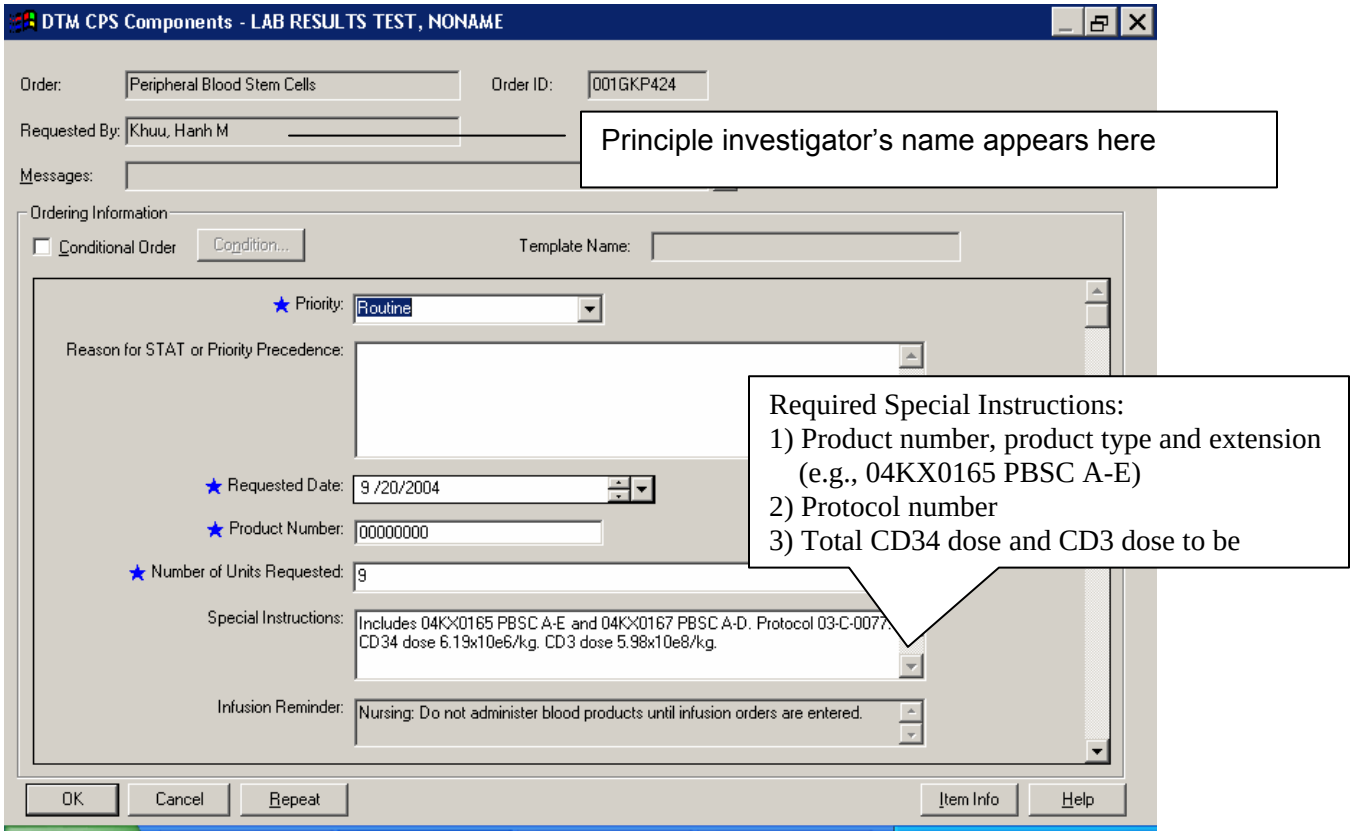
Note: One unit is defined as one aliquot for the infusion event. Each aliquot has a unique extension or no extension (e.g., PBSC A, Lymph B or PBSC)

Enter total number of "units" to be infused of the same component type, even if multiple product numbers are involved.

Example: 04KS0143 PBSC A-F = 6 units
04KS0147 PBSC A-B = 2 units
If both products are ordered for infusion, enter 8 units.

Special Instructions- Required by CPS

1) Product number and product type and extension
2) Protocol number for which processing was performed
3) Request for additional manipulations such as T cell addback
4) Total CD34 dose and/or total CD3 dose to be infuse
5) Contact person & number for issues or concerns about the product to be in fused (i.e., dose, sterility issue or abnormal test result)



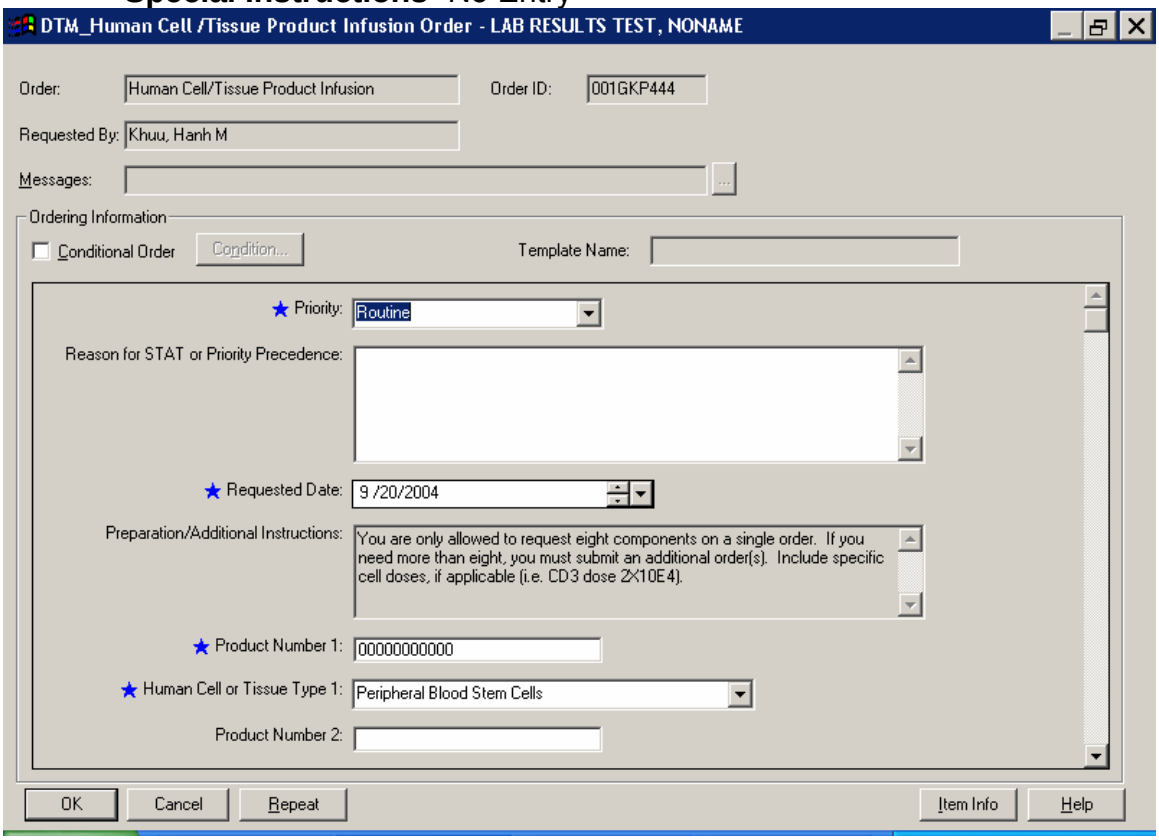
6) If **DTM CPS Components** order is complete click **OK** in lower left corner.

7) Order Set Summary appear: select **Infusion Order**→ select **EDIT**→ **DTM Human Cell/Tissue Product Infusion** appears (highlighted areas require entry):

Priority- Routine
Reason for Stat or Priority Precedence- No Entry
Requested Date- Date of Infusion
Preparation/Additional Instructions- No Entry (request to delete field pending)
Product Number- Enter alpha numeric identifier
Human Cell and Tissue Type- Enter product type from drop list

Note: If order consists of more than one product type, enter primary product type for infusion (e.g., PBSC with T-cell addback, select PBSC only). Refer to Summary of Clinical Products (DTM-FORM-5111) for list of available components.

Special Instructions- No Entry



8) After **DTM Human Cell/Tissue Product Infusion Order** is complete click the **OK** button in the lower left corner.

9) Order Set Summary appears. Click **OK.**

10) **Order Entry Worksheet** reappears. Click **Submit.**

11) After order is submitted, click **Orders** tab. Clinical Manager appears with appropriate orders listed under **Transfusion Medicine** with **Pending** status.

12) Manual order entry for CPS order set is now complete.

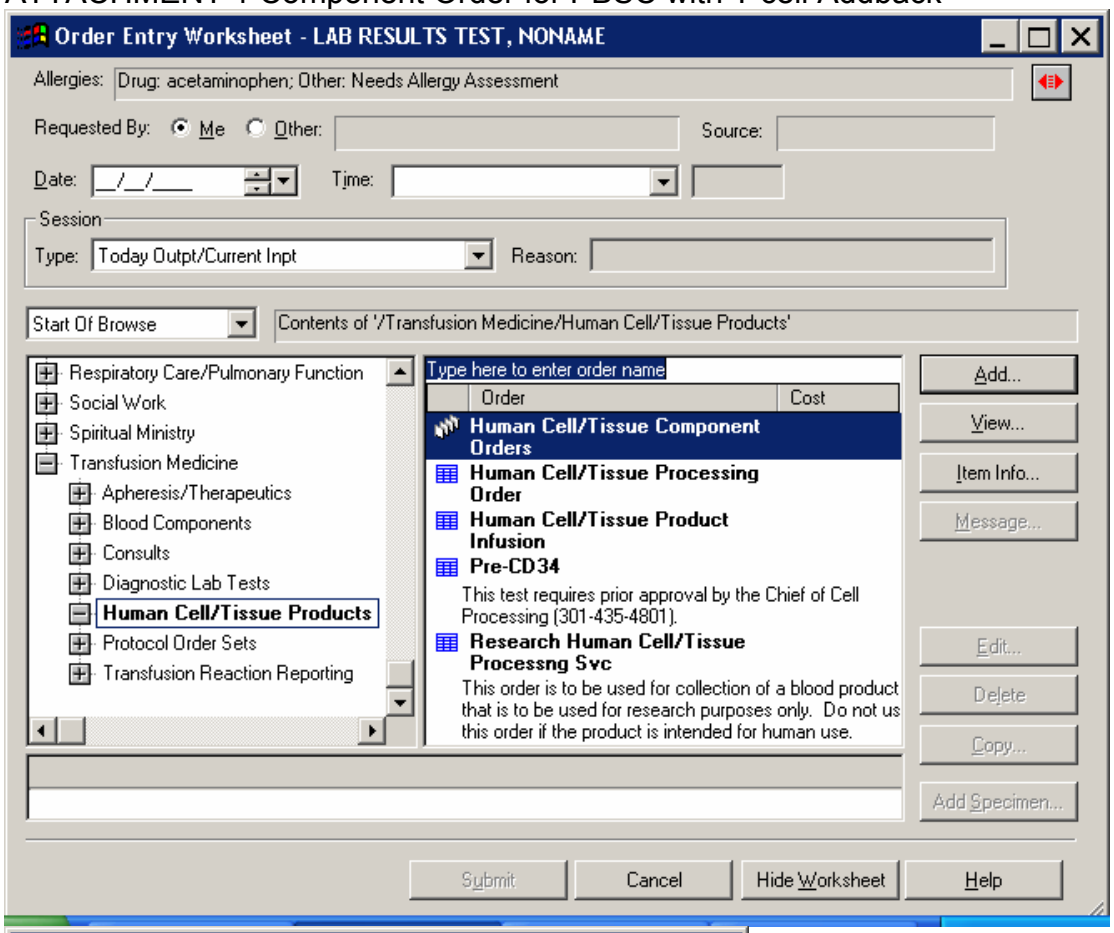
3. ATTACHMENTS

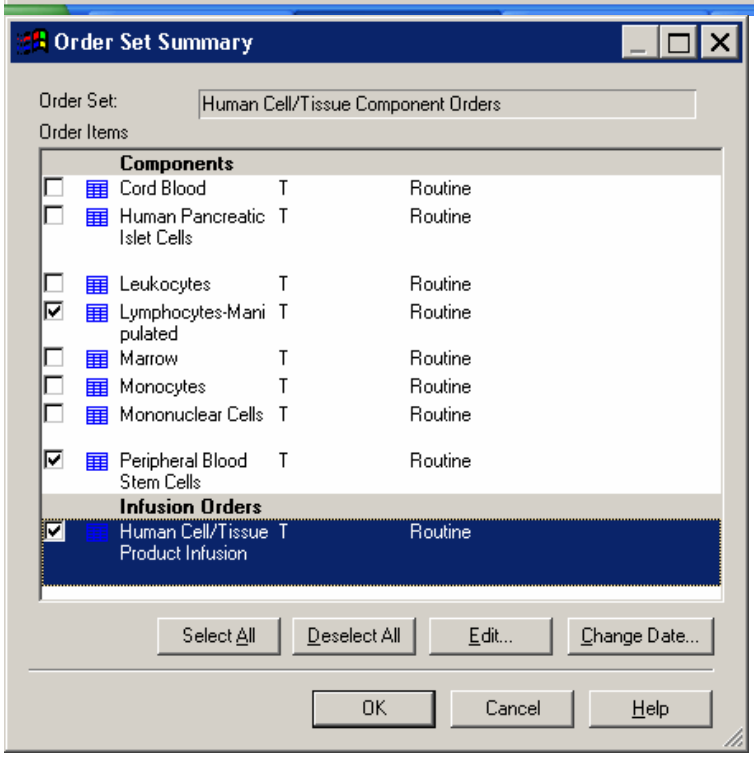
ATTACHMENT 1: PBSC with T-cell addback component order

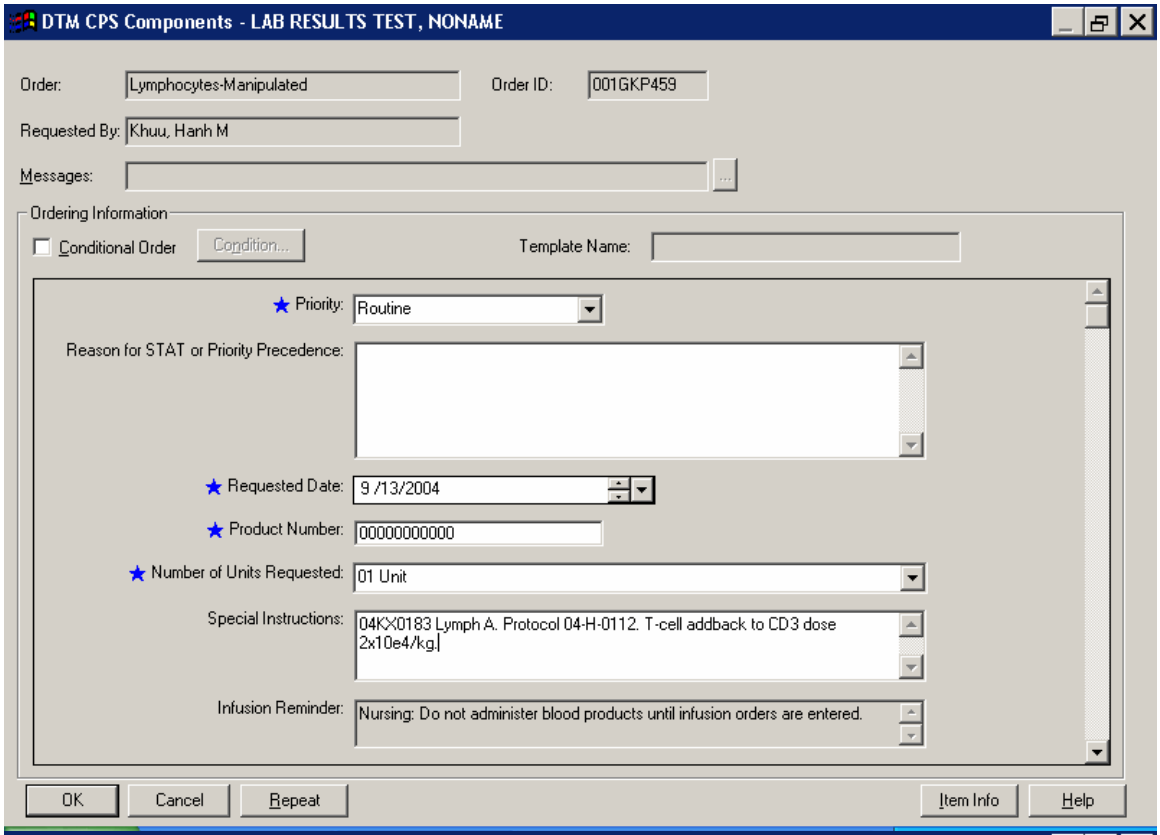
4. REFERENCES:

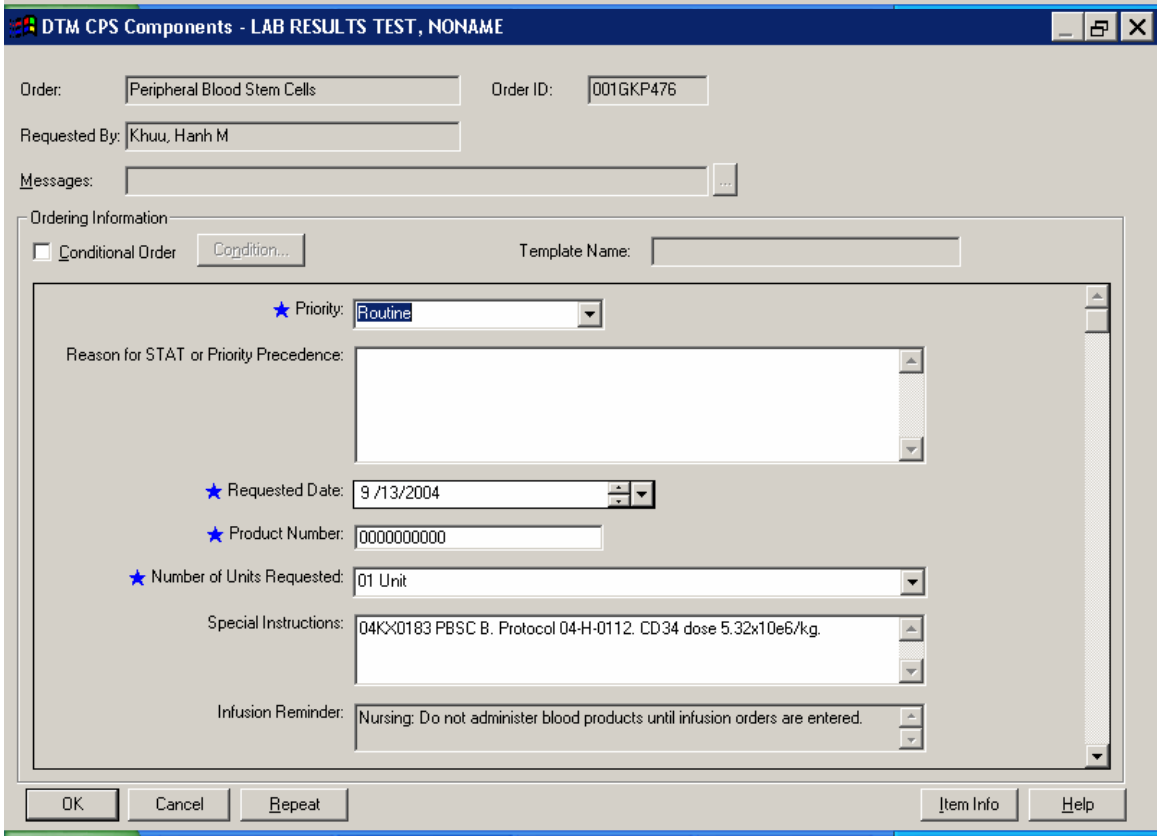
CRIS Practice Exercise Workbook, Non-Prescriber Order Entry, NIH, 2004.

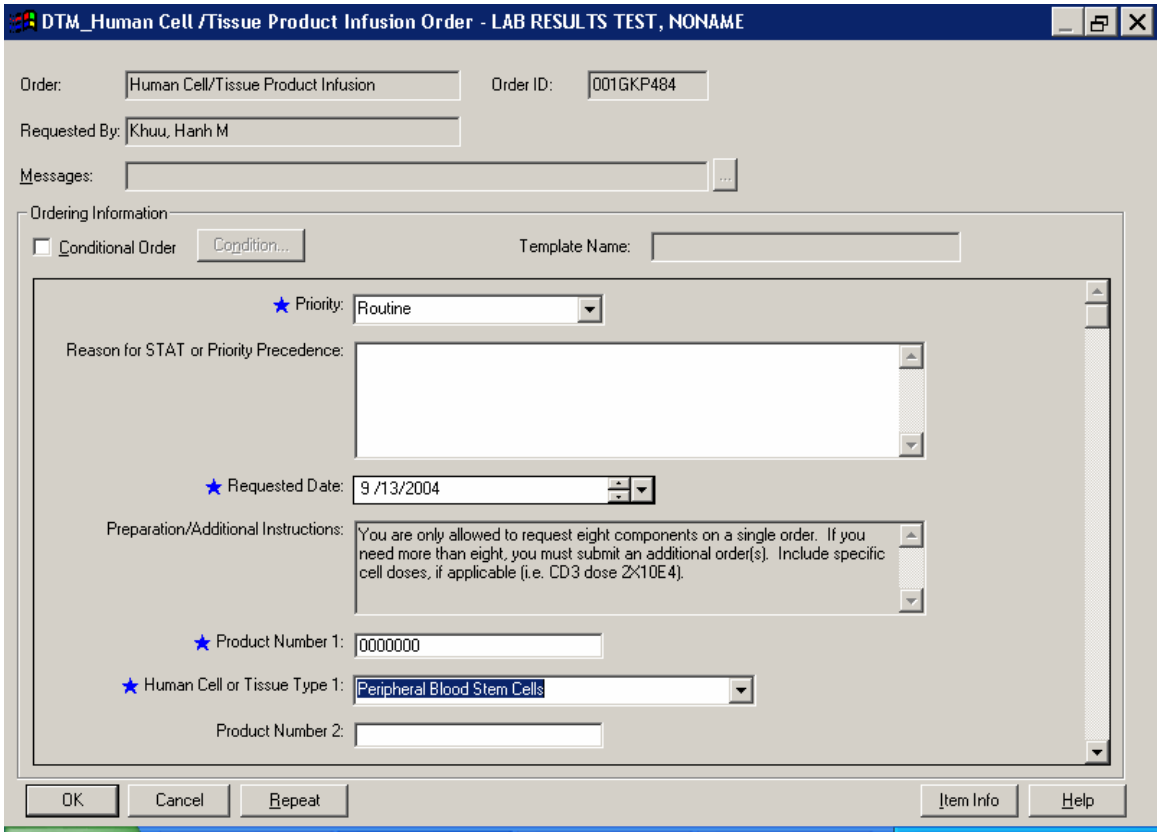
ATTACHMENT 1 Component Order for PBSC with T cell Addback






DTM CPS Components - LAB RESULTS TEST, NONAME
Order: Lymphocytes-Manipulated
Order ID: 001GKP459
Requested By: Khuu, Hanh M
Messages:
Ordering Information
Conditional Order
Condition...
Template Name:
Priority: Routine
Reason for STAT or Priority Precedence:
Requested Date: 9 /13/2004
Product Number: 00000000000
Number of Units Requested: 01 Unit
Special Instructions: 04KX0183 Lymph A. Protocol 04-H-0112. T-cell addback to CD3 dose 2x10e4/kg.
Infusion Reminder: Nursing: Do not administer blood products until infusion orders are entered.
OK
Cancel
Repeat
Item Info
Help


DTM CPS Components - LAB RESULTS TEST, NONAME
Order: Peripheral Blood Stem Cells
Order ID: 001GKP476
Requested By: Khuu, Hanh M
Messages:
Ordering Information
Conditional Order
Condition...
Template Name:
Priority: Routine
Reason for STAT or Priority Precedence:
Requested Date: 9 /13/2004
Product Number: 0000000000
Number of Units Requested: 01 Unit
Special Instructions: 04KX0183 PBSC B. Protocol 04-H-0112. CD34 dose 5.32x10e6/kg.
Infusion Reminder: Nursing: Do not administer blood products until infusion orders are entered.
OK
Cancel
Repeat
Item Info
Help


DTM_Human Cell /Tissue Product Infusion Order - LAB RESULTS TEST, NONAME
Order:
Human Cell/Tissue Product Infusion
Order ID:
001GKP484
Requested By:
Khuu, Hanh M
Messages:
Ordering Information
Conditional Order
Condition...
Template Name:
Priority:
Routine
Reason for STAT or Priority Precedence:
Requested Date:
9 /13/2004
Preparation/Additional Instructions:
You are only allowed to request eight components on a single order. If you need more than eight, you must submit an additional order(s). Include specific cell doses, if applicable (i.e. CD3 dose 2X10E4).
Product Number 1:
0000000
Human Cell or Tissue Type 1:
Peripheral Blood Stem Cells
Product Number 2:
OK
Cancel
Repeat
Item Info
Help

INSTRUCTION # 5118-7

Access/Viewing CRIS Orders

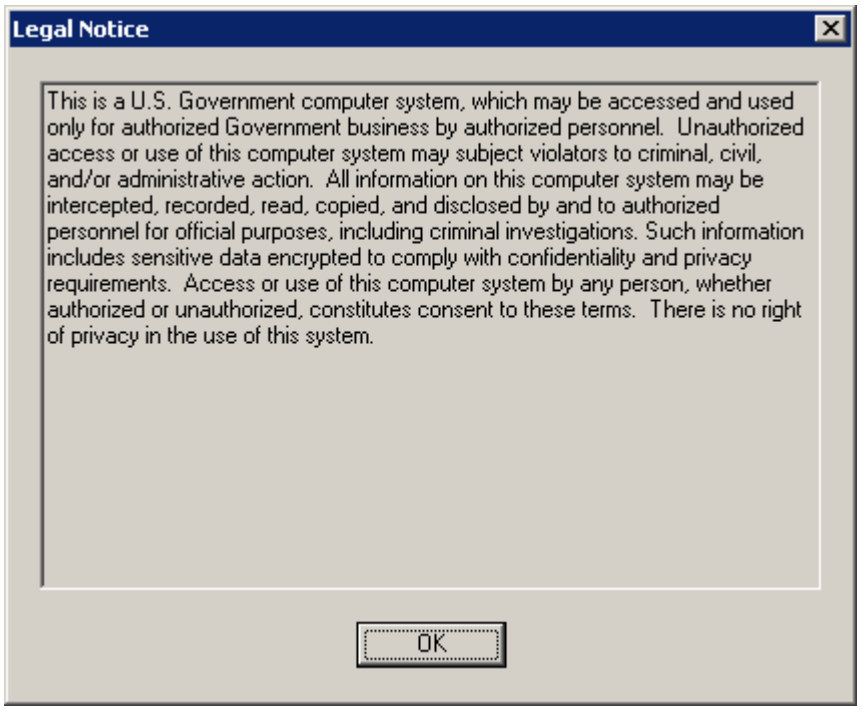
1. SCOPE:

The CRIS operating system is a web based application and should be accessed to perform specified functions in the manufacture of HCT/Ps. This procedure will outline the steps to sign into CRIS, locate a patient, create a temporary list, and view orders entered for the patient of interest.

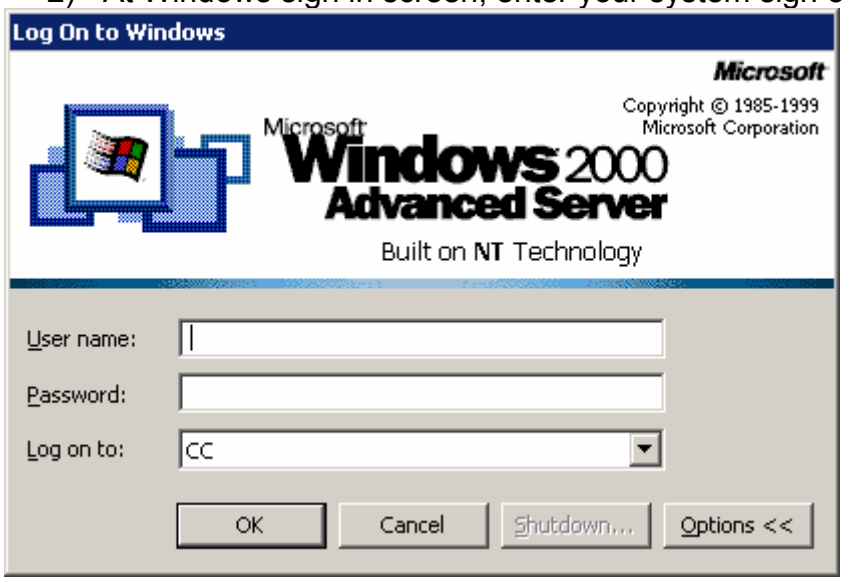
2. PROCEDURE:

2.1 Access to CRIS

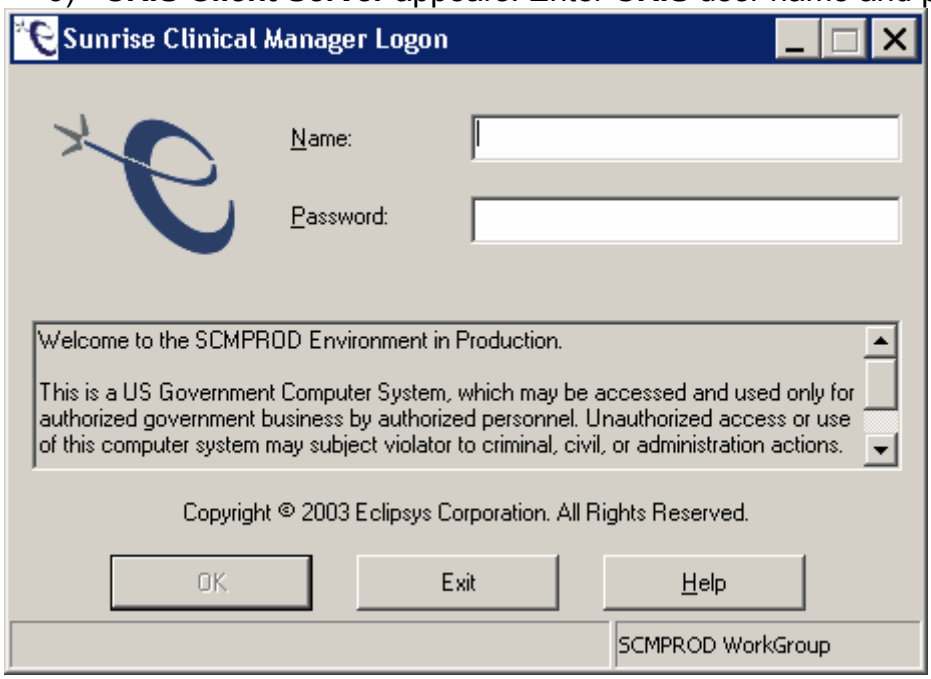
1) Left double click on **CRIS** icon from your local workstation to start Citrix. Click **OK**.



2) At Windows sign in screen, enter your system sign on user name and password.



3) **CRIS Client Server** appears. Enter **CRIS** user name and password. Select **OK**.

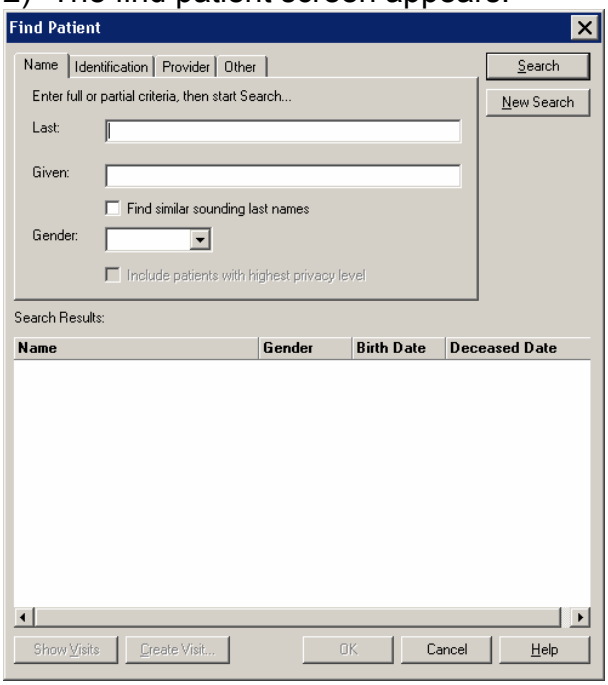


4) A CRIS default screen appears.

2.2 To locate a patient:

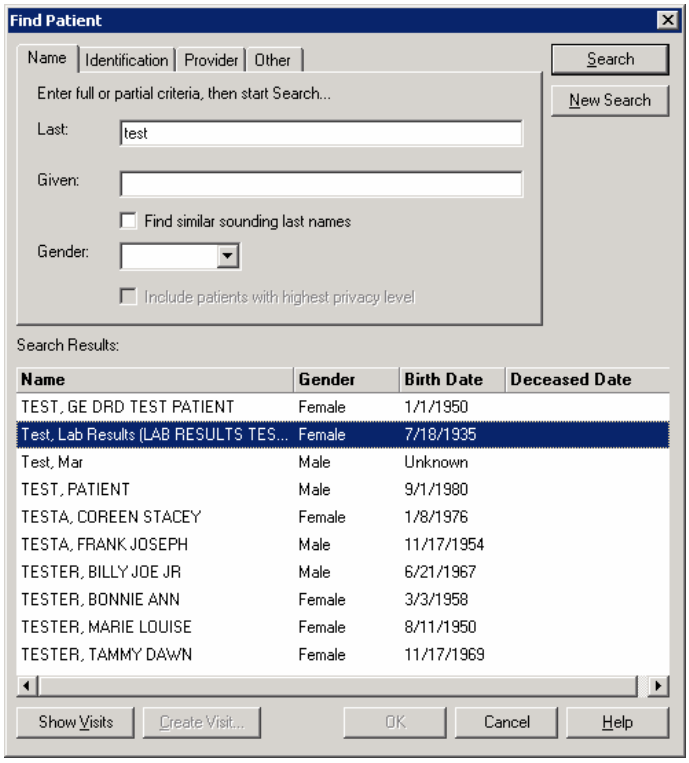
1) To locate a patient, click on **Find patient** icon.

2) The find patient screen appears.

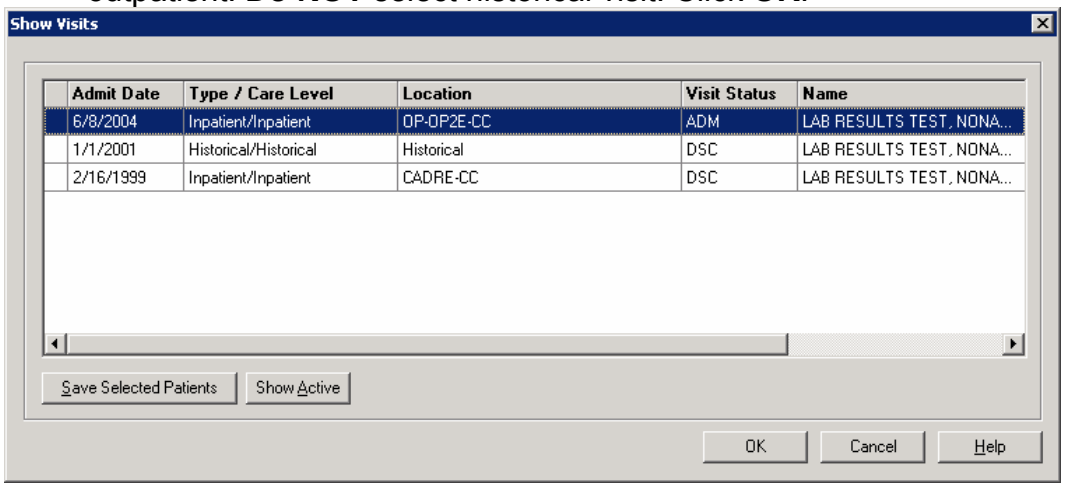


3) Type patient's last name, given or first name and click **Search**.

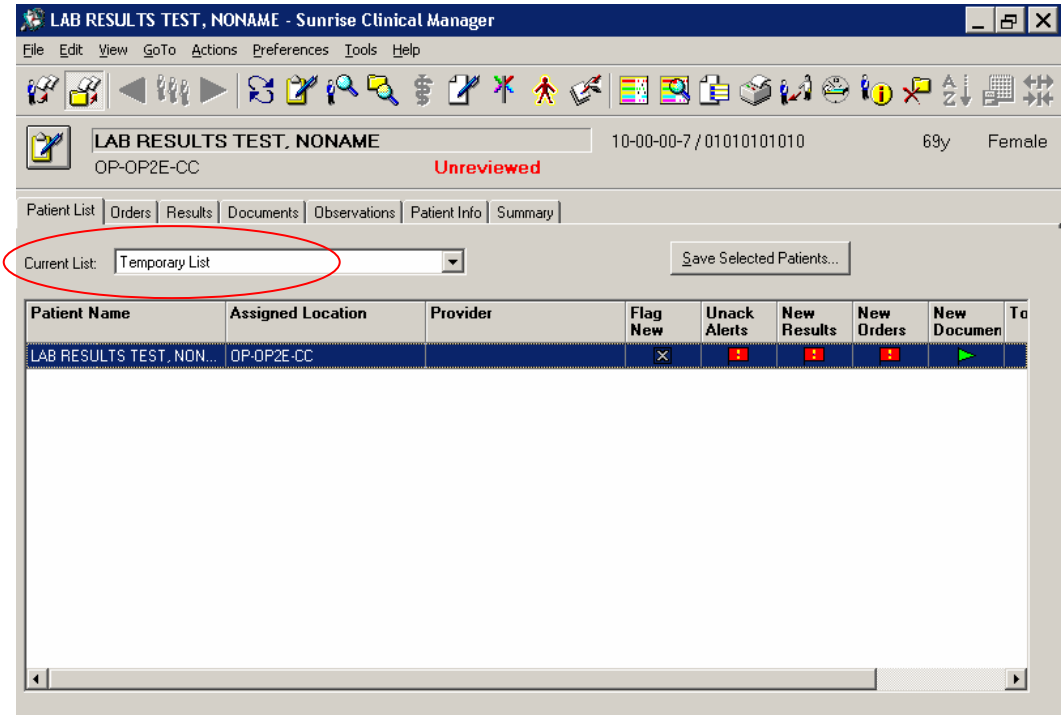
4) One or more patients with same last name will appear. Select patient of interest and click **Show Visits**.



5) Show visits screen appears. Select visit with most recent date, either inpatient or outpatient. **Do NOT** select historical visit. Click **OK**.



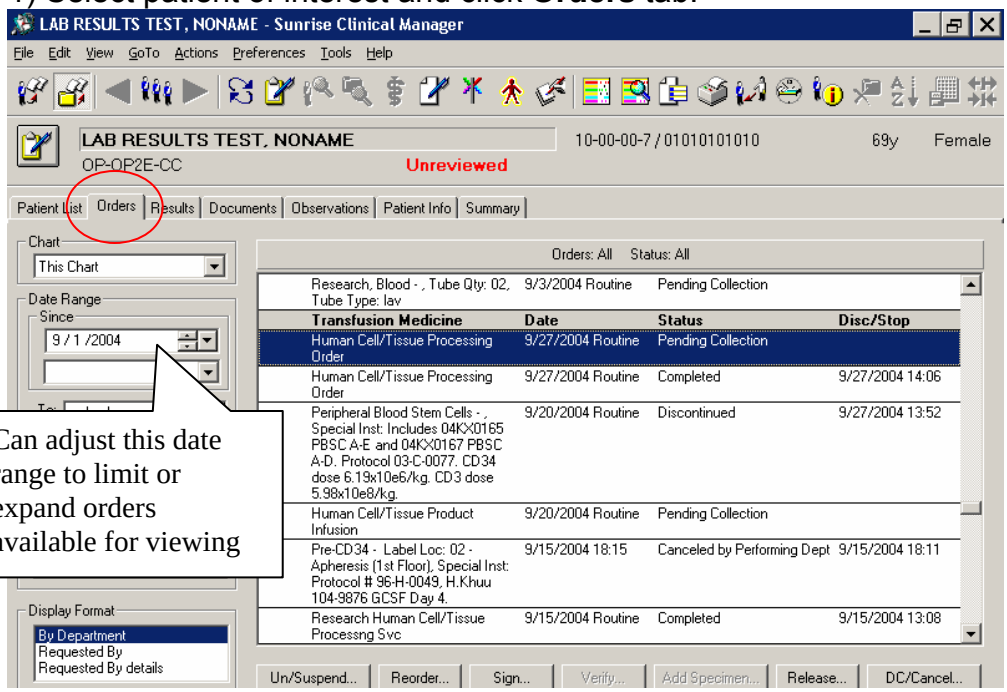
6) A temporary list of patients is generated.



Note: To add additional patients to temporary list, repeat steps 1-6.

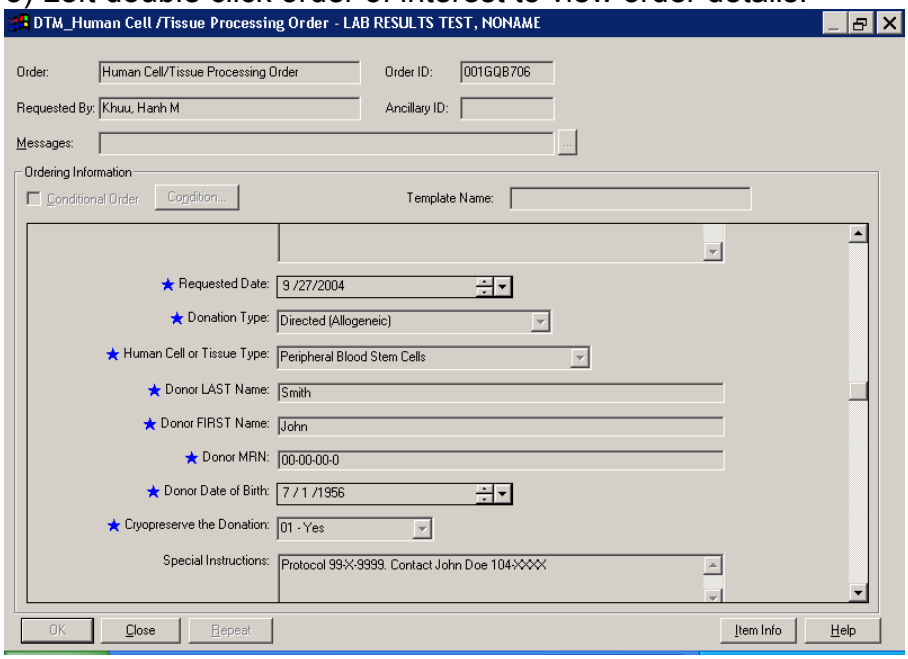
2.3 To view orders for a patient:

1) Select patient of interest and click **Orders** tab.



2) Select order of interest by moving scroll bar up and down.

3) Left double click order of interest to view order details.



3. REFERENCES:

CRIS User Guide, NIH, 2004.

INSTRUCTION # 5118-8

Generating Admission Demographic Labels

1. SCOPE:

Due to numerous processing documents used within CPS daily operations, the ability to print donor and recipient demographic labels is a necessity. The labels include name, MRN (Medical Record Number), birthdate and miscellaneous demographic information such as age, race and gender. The labels generated are used for document labeling and are not a substitute for any other type of demographic label generated within CPS operations (e.g., sterility testing or micro. orders).

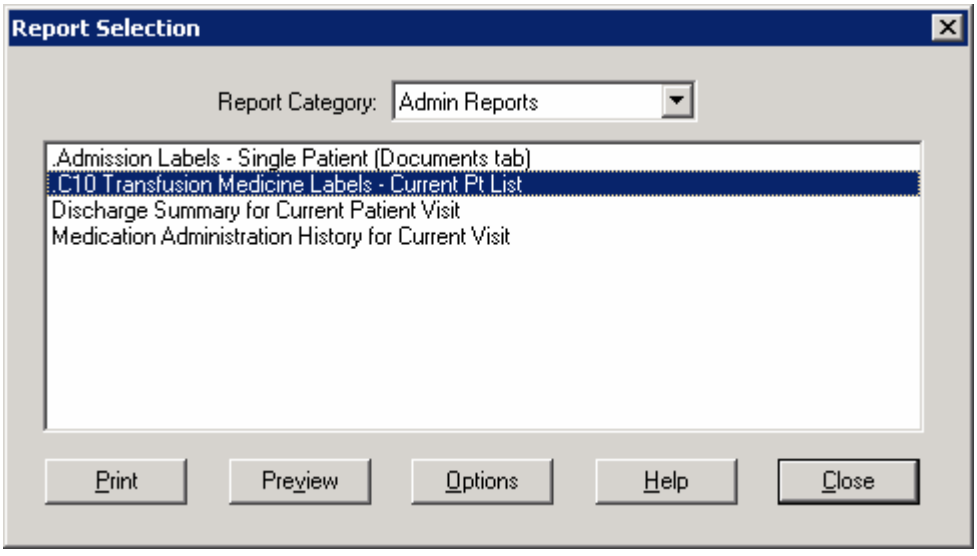
2. PROCEDURE:

2.1 Generating Admission Demographic Labels

1) Locate patient per instructions outlined in 5118-7 CRIS Access/Viewing Orders**.**

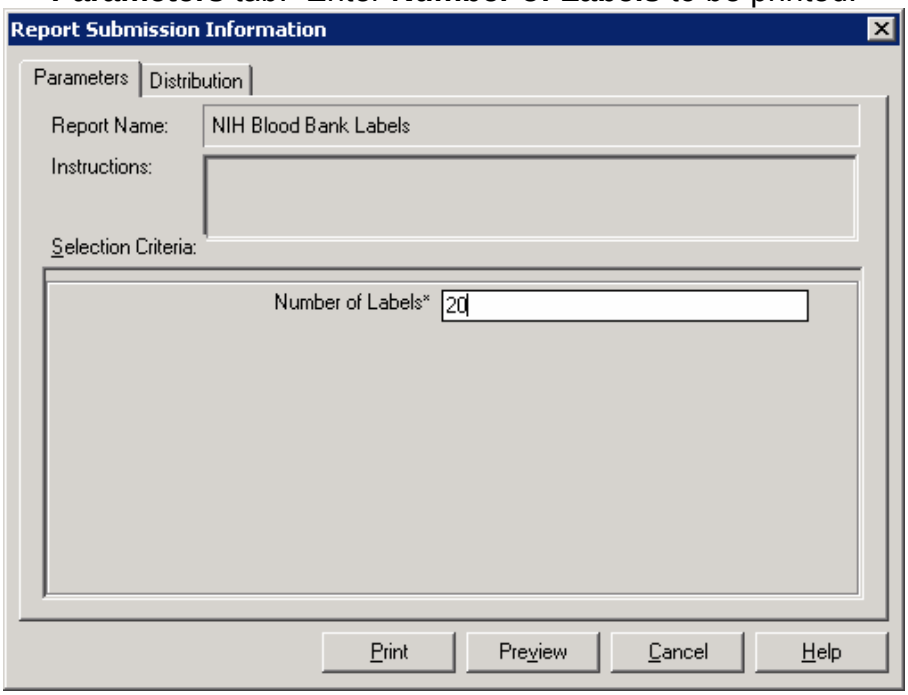
2) Click **Print Reports** icon on toolbar.

3) A **Report Selection** window appears. Within Report Category, select **Admin. Reports** from drop list.

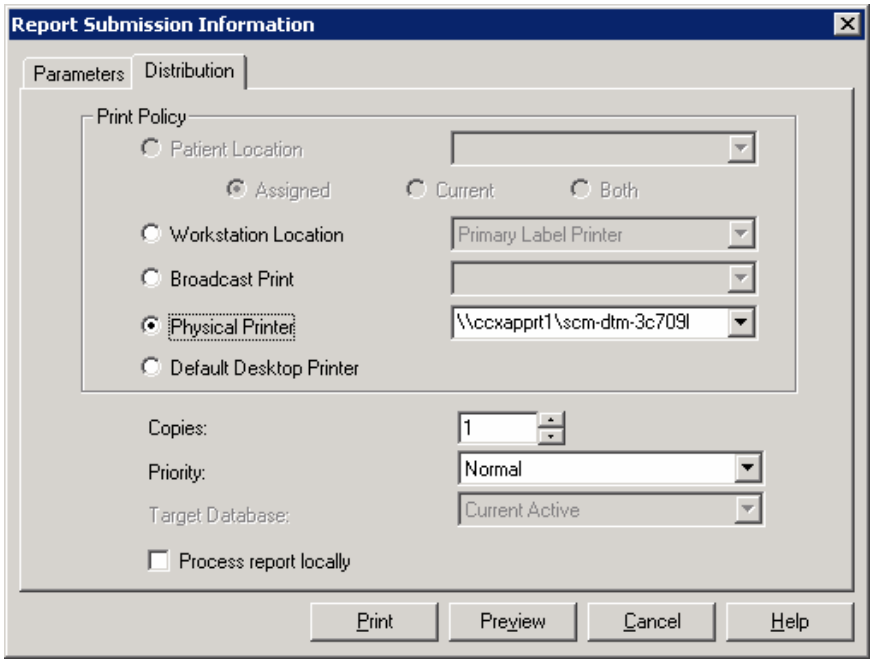


4) Within **Admin. Reports**, select **C10 Transfusion Medicine Labels – Current Pt List and** click **Options**.

5) The **Report Submissions Information** screen appears and defaults to **Parameters** tab. Enter **Number of Labels** to be printed.

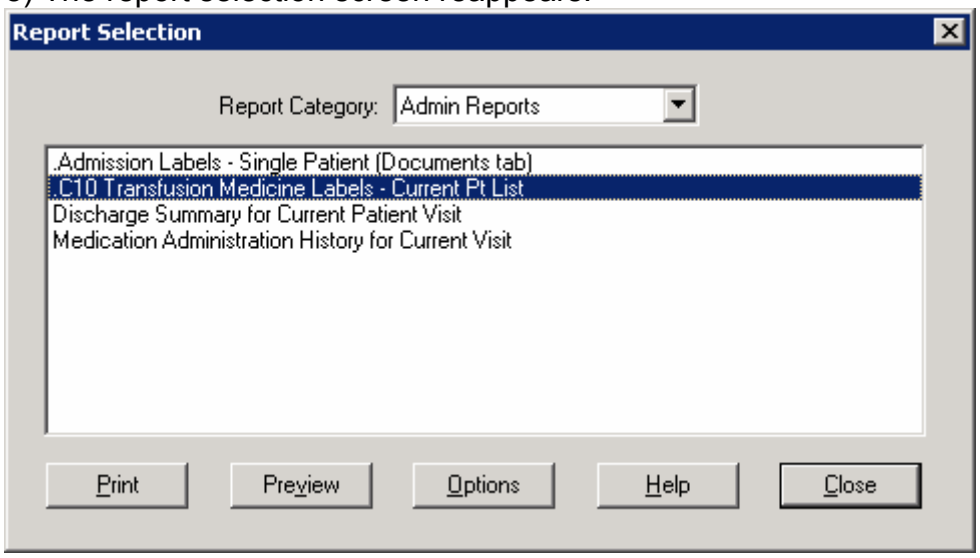


6) Click on **Distribution** tab. Click on radial button for **Physical Printer**. Enter full name of label printer \\ccxapprt1\scm-dtm-3c709L. Click **Print**.



7) **Note**: Do **not** change any other settings within the screen.

8) The report selection screen reappears.



9) Click **Close**.

10) Retrieve labels from designated label printer.

3. REFERENCES:

CRIS User Manual, NIH, 2004.

INSTRUCTION # 5118-9
Completing/Canceling CRIS Order

1. SCOPE:

CRIS orders that do not require resulting, must be either completed or cancelled in the system. Once a CPS order set has been verified and the process has been finished, CPS staff must return to Patient List Display summary to finalize the donor or assigned patient/recipient order.

2. PROCEDURE:

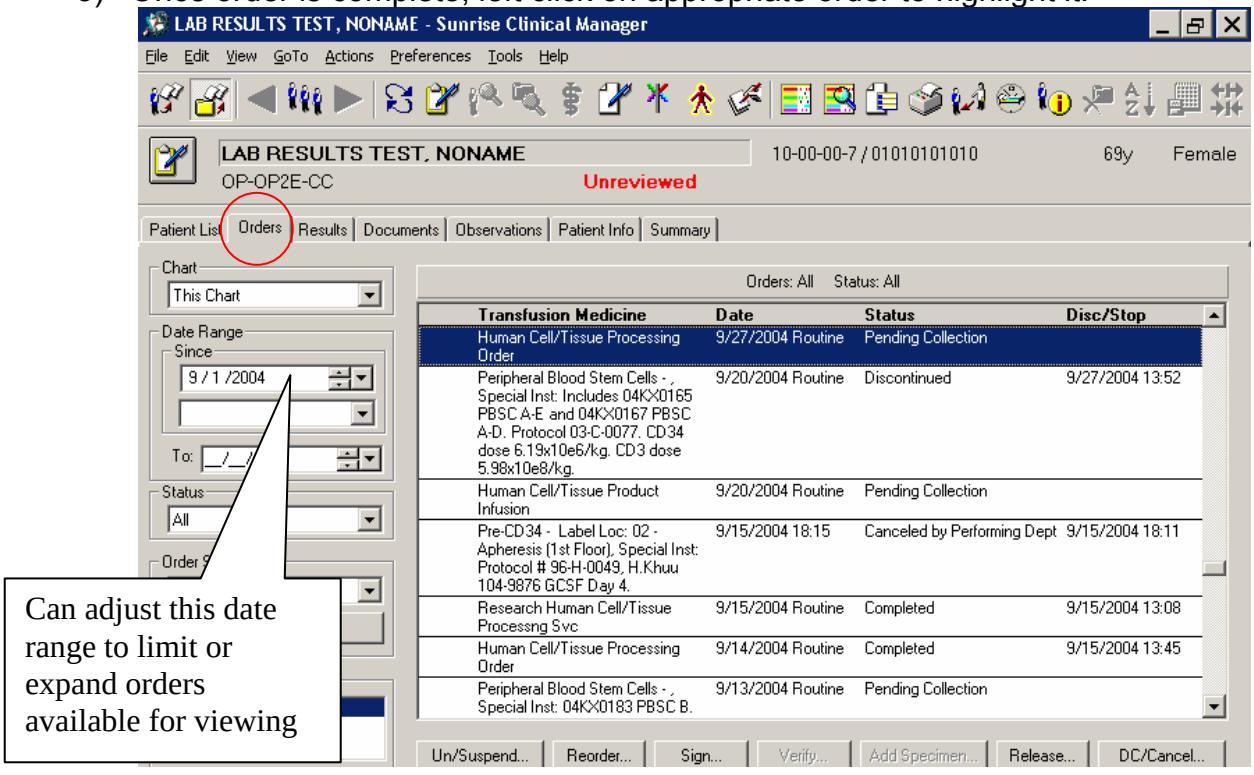
2.1 Completing the (Processing) Order

NOTE: Component orders are completed in CRIS when orders are "finished" in Softbank. "Completing" order in CRIS consists of verifying "final" status in CRIS.

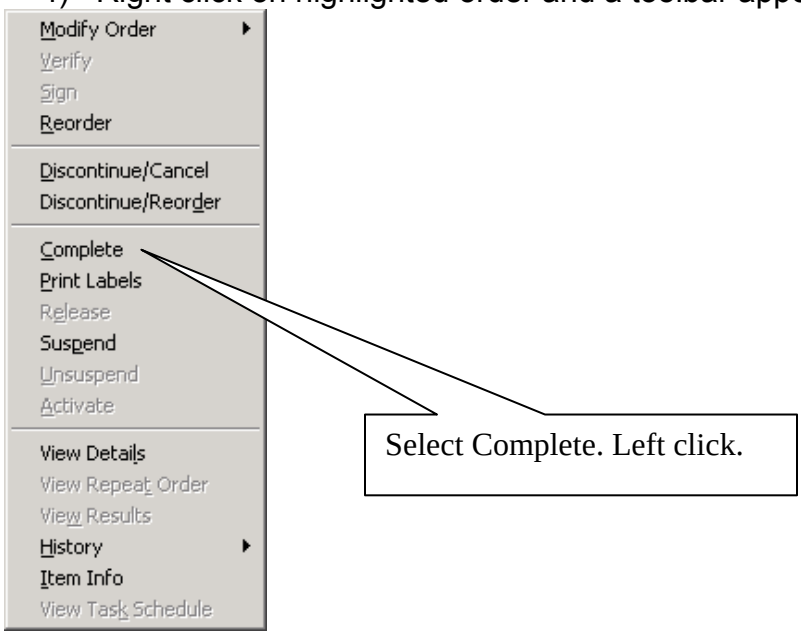
1) Select donor or assigned patient/recipient from **Patient List Display**.

2) With the donor or assigned patient/recipient selected, click **Order** tab.

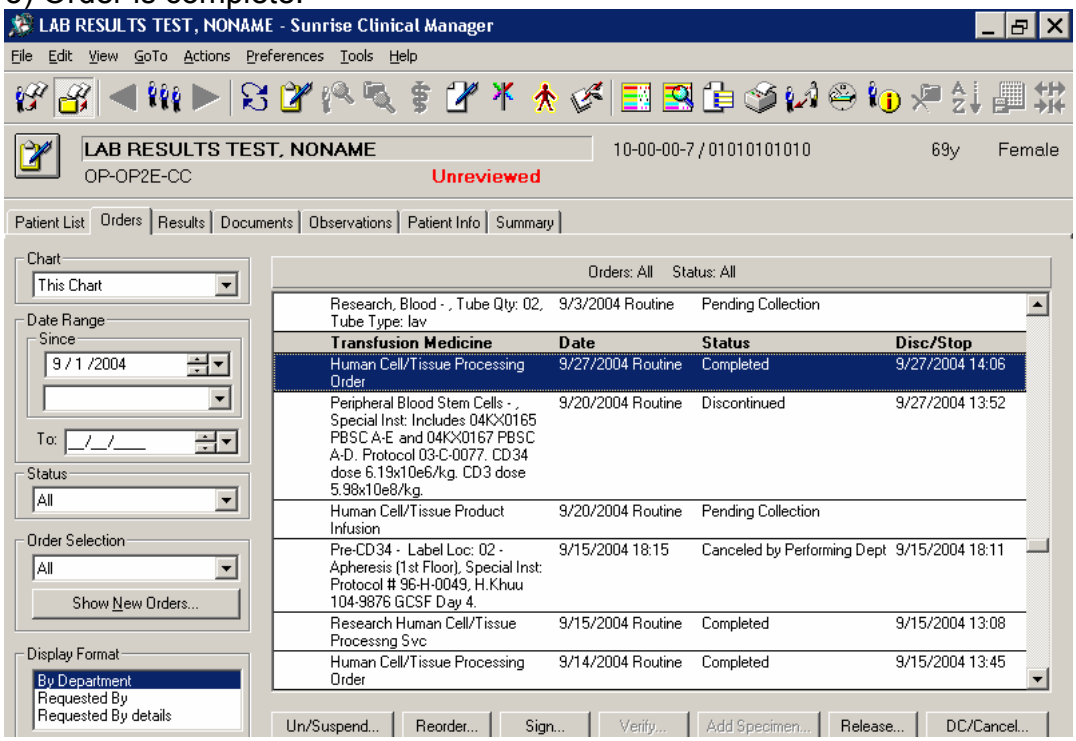
3) Once order is complete, left click on appropriate order to highlight it.



4) Right click on highlighted order and a toolbar appears.



5) Order is complete.

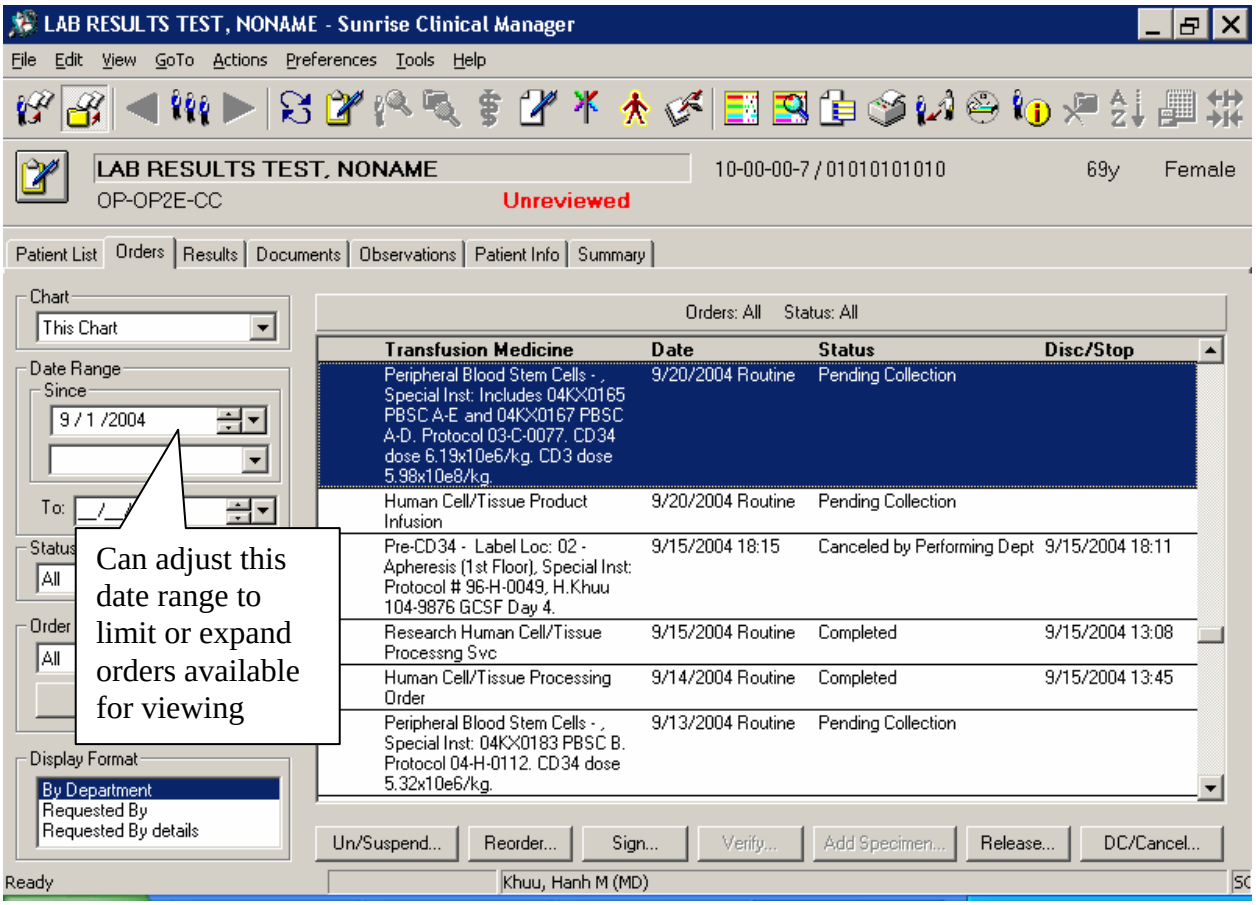


2.2 Canceling an Order

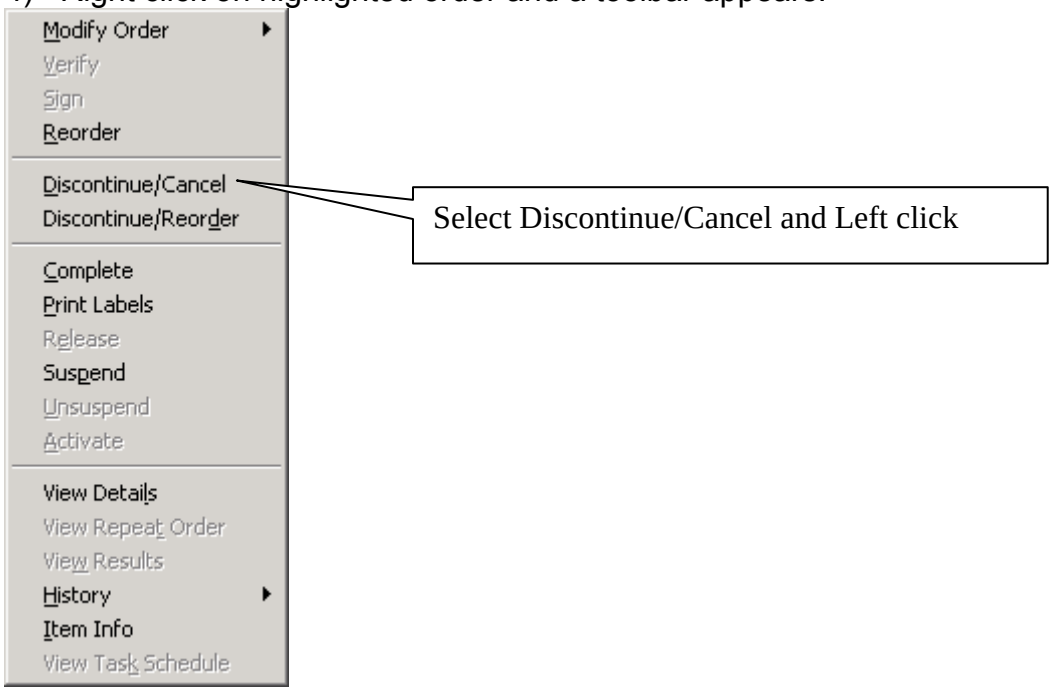
1) Select donor or assigned patient/recipient from **Patient List Display**.

2) With donor or assigned patient/recipient selected, click **Order** tab

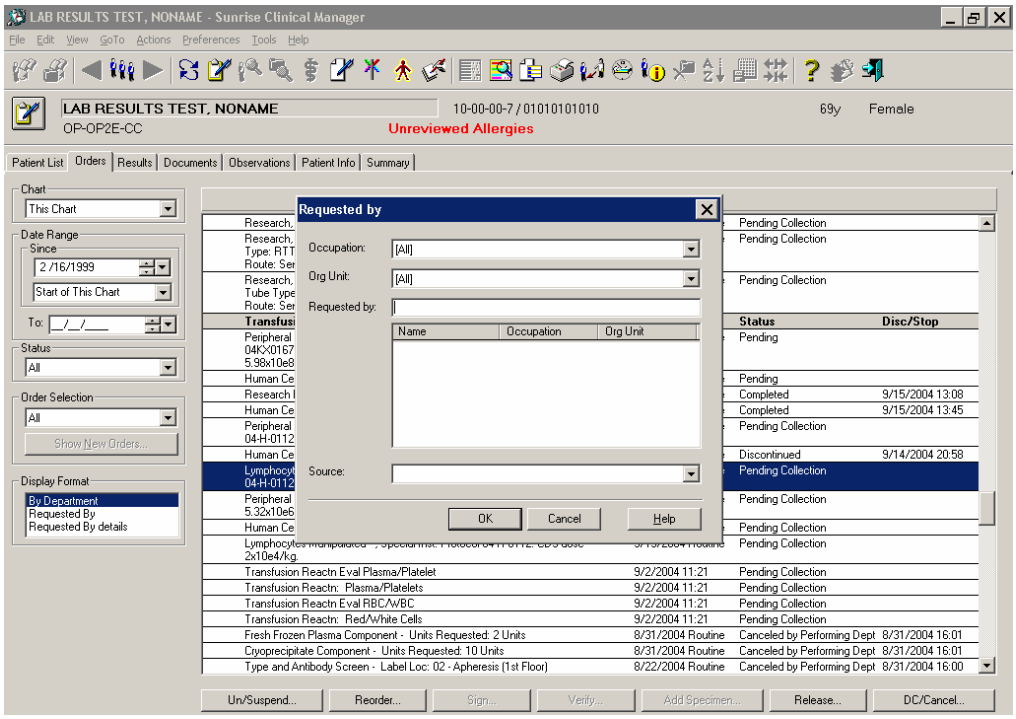
3) Once order is completed, left click on appropriate order to highlight it.



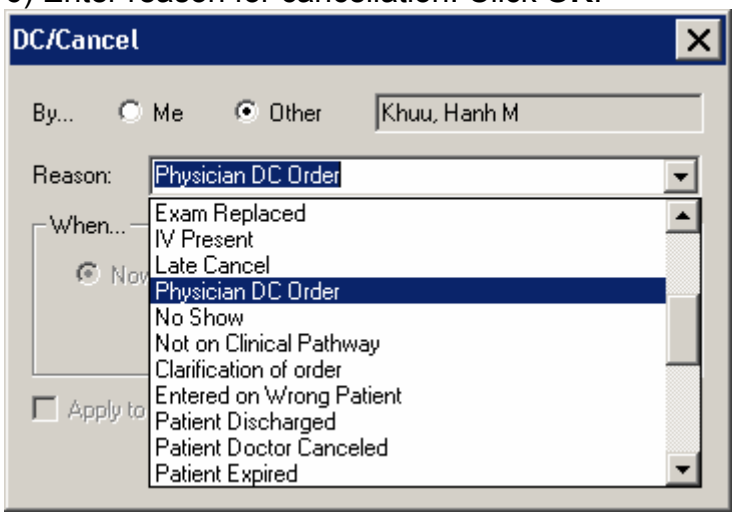
4) Right click on highlighted order and a toolbar appears.



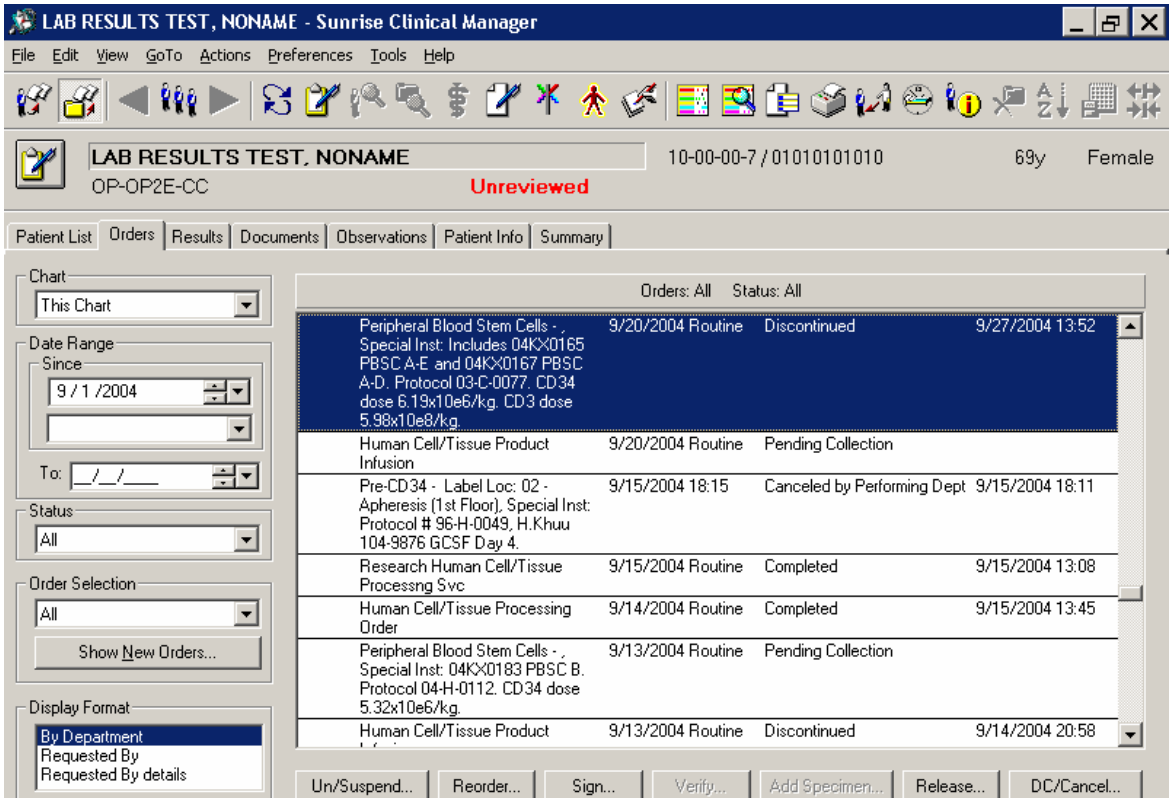
5) "Requested By" screen appears. Enter PI's last name. Select **Verbal** as "Source". Click OK.



6) Enter reason for cancellation. Click **OK**.



7) Order is cancelled.



3. REFERENCES:

CRIS Practice Exercise Workbook, Non-Prescriber Order Entry, NIH, 2004.